

REMARKS

Entry of the foregoing amendments is respectfully requested.

Summary of Amendments

Upon entry of the foregoing amendments claim 48 is amended, claims 49-53, 57-60, 64 and 69-71 are cancelled and claims 72-83 are added, whereby claims 48, 54-56, 61-63, 65-68 and 72-83 will be pending, with claim 48 being the only independent claim.

Support for the amended and new claims can be found throughout the present specification and in the cancelled claims.

Applicants emphasize that the amendment to claim 48 and the cancellation of claims 49-53, 57-60, 64 and 69-71 are without prejudice or disclaimer, and Applicants expressly reserve the right to prosecute the cancelled claims and amended claim 48 in its original, unamended form in one or more continuation and/or divisional applications.

Applicants submit that entry of the present amendments is proper because they do not raise any new issues and do not require any further search.

Summary of Office Action

As an initial matter, Applicants note with appreciation that the Examiner appears to have withdrawn the rejection of claims 65 and 69-71 under 35 U.S.C. § 112, second paragraph.

Claims 48, 49, 54, 60-62 and 65-71 remain rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

Claims 48, 49, 54, 61, 62, 65-69 and 71 remain rejected under 35 U.S.C. § 103(a) as

allegedly being unpatentable over Lilley et al., GB 2 359 746 (hereafter “LILLEY”).

Claims 60 and 70 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over LILLEY in view of Gail B. Mahady, Thai Journal of Phytopharmacy, Vol. 9(1), pp. 50-62 (hereafter “MAHADY”).

Response to Office Action

Reconsideration and withdrawal of the rejections of record are respectfully requested, in view of the foregoing amendments and the following remarks.

Response to Rejection under 35 U.S.C. § 112, First Paragraph

Claims 48, 49, 54, 60-62 and 65-71, i.e., all claims under consideration, remain rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The rejection essentially repeats the allegations set forth in the previous Office Action and again asserts that the specification, while being enabling for a method of treating a microbe-caused disease of at least one skin condition disclosed in the instant claims, allegedly does not reasonably provide enablement for preventing a microbe-caused disease.

This rejection is respectfully traversed for all of the reasons which are set forth in the responses to the previous Office Actions. The corresponding remarks are expressly incorporated herein.

Applicants still are unable to share the Examiner’s opinion that the use of oil of coriander is not enabled for a method regarding the *prevention* of a microbe-caused disease. There is no need for undue experimentation (if experimentation is necessary at all) for one of ordinary skill

in the art to practice the claimed method. A person of ordinary skill in the art knowing about the effectiveness of oil of coriander in the treatment of a microbe-caused disease could and certainly would rely on the effectiveness of oil of coriander in preventing such a disease. The former can doubtlessly be derived from the instant specification, as acknowledged by the Examiner.

In this regard, Appellants also note the guidance provided by MPEP 2164.06 (underlining provided):

The quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether "undue experimentation" is required to make and use the invention. "[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). Time and expense are merely factors in this consideration and are not the controlling factors. *United States v. Teletronics Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989).

Applicants submit that for at least all of the foregoing reasons and the additional reasons set forth in the responses to the previous Office Actions, the rejection under 35 U.S.C. § 112, first paragraph, for alleged failure to comply with the enablement requirement is without merit and should be withdrawn, which action is again respectfully requested.

Response to Rejection under 35 U.S.C. § 103(a) over LILLEY

Claims 48, 49, 54, 61, 62, 65-69 and 71 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over LILLEY. The Office essentially repeats the allegations set forth in the previous Office Action. The rejection again concedes that LILLEY does not teach the

step of administering coriander oil to a mammal but alleges that it would have been obvious to one of ordinary skill in the art to administer oil of coriander to a mammal based on the teachings provided by LILLEY. The rejection further asserts again that the oral cavity comprises skin, alleging that “[t]he oral cavity has an epithelial covering and thus read[s] on skin”. Page 10, first paragraph of the instant Office Action.

Applicants respectfully traverse this rejection for all the reasons which are set forth in the responses to the previous Office Actions. The corresponding remarks are expressly incorporated herein. At any rate, the rejected claims are cancelled, wherefore this rejection is moot.

Applicants still strongly disagree with the Examiner’s position that the oral cavity comprises skin. Clearly, not everything that comprises an epithelium qualifies as “skin”. A person skilled in dermatology is aware that skin comprises (i) *epidermis* (containing keratinized squamous epithelium cells), (ii) *dermis/corium* and (iii) *subcutis*, whereas a mucous membrane (as present in the oral cavity) consists of a non-keratinized epithelium (*Lamina epithelialis mucosae*) and a particular Lamina (*Lamina propria mucosae*).

In this regard see also the entry for “skin” in <http://www.britannica.com/EBchecked/topic/547591/human-skin> (accessed on the Internet on July 20, 2011, emphasis added):

Surface covering of the body that protects it and receives external sensory stimuli, consisting of an epidermis over a thicker dermis.

The epidermis contains cells involved in immune defenses, sensory receptors, pigment cells, and keratin-producing cells. The last harden and migrate to the surface to form a dead, relatively dry outer layer of horny tissue that constantly sloughs away. The dermis contains sensory nerves and blood vessels within connective tissue. Collagen and elastin fibres give skin its tough, elastic quality. Cells scattered through it produce its components and take part in immune and other skin responses. A fat layer under the dermis provides

nutritional storage, cushioning, and insulation. Skin disorders range from dermatitis and acne to skin cancer. Changes in skin colour (e.g., jaundice) or texture may be clues to systemic disorders.

and the entry for “mucous membrane” in <http://www.britannica.com/EBchecked/topic/395887/mucous-membrane> (accessed on the Internet on July 20, 2011, emphasis added):

membrane lining bodily cavities and canals that lead to the outside, chiefly the respiratory, digestive, and urogenital tracts. Mucous membranes line many tracts and structures of the body, including the mouth, nose, eyelids, windpipe and lungs, stomach and intestines, and the ureters, urethra, and urinary bladder. The membranes vary in structure, but they all have a surface layer of epithelial cells over a deeper layer of connective tissue. They are called mucous because they contain cells that secrete mucin, a mucopolysaccharide that is the principal constituent of mucus.

In view of the foregoing facts, there can be no reasonable doubt that one of ordinary skill in the art does not consider the oral cavity to comprise “skin”. Further, in view of the significant (structural) differences between skin and a mucous membrane there is no basis for assuming that skin and a mucous membrane are comparable in any respect and in particular, that microbes (bacteria) that are present in the oral cavity and microbes on the skin are similar enough to respond to a given antibacterial agent in the same way. Neither has the Examiner presented any evidence that there are antibacterial treatments that are effective for treating/preventing periodontal disease/malodor in the oral cavity (as disclosed by LILLEY) which at the same time are known to also be effective in the prophylaxis/treatment of any skin diseases.

Response to Rejection under 35 U.S.C. § 103(a) over LILLEY in View of MAHADY

Claims 60 and 70 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over LILLEY in view of MAHADY. The rejection again concedes that LILLEY

fails to teach that the alleged microbe-caused disease disclosed therein is associated with a Methicillin-resistant *Staphylococcus aureus* and/or a multi-resistant pathogen but essentially alleges that MAHADY cures this deficiency of LILLEY, asserting, *inter alia*, that MAHADY “teaches that such pathogens can become multi-resistant to the over use of antibiotics and therefore need an alternative treatment[] as in essential oils that include coriander”.

Applicants respectfully traverse this rejection as well, for all of the reasons which are set forth in the responses to the previous Office Actions. The corresponding remarks are expressly incorporated herein.

In particular, it still is not seen that one of ordinary skill in the art would assume that the “species of bacteria which are strongly implicated in periodontal disease and/or malodour production” of LILLEY and Methicillin-resistant *Staphylococcus aureus* and/or multi-resistant pathogens have anything in common and in particular, would respond to the same treatment.

It is pointed out again that MAHADY mentions Methicillin-resistant *Staphylococcus aureus*/multi-resistant pathogens only in a general context, merely stating that “development of resistance in some human pathogens, such as methicillin-resistant *Staphylococcus aureus* and multi-drug resistant *Mycobacterium tuberculosis*, is linked to the use of antimicrobials in man”. This is merely a neutral statement of the authors of MAHADY and, without applying hindsight, in no way a suggestion, let alone a teaching, that multi-resistant pathogens can be inhibited by oil of coriander (even if they developed from an overuse of antibiotics), i.e., a substance that is mentioned in MAHADY only as one of about 100 plant species from Thailand with antimicrobial activity.

It further is noted that among the bacterial test pathogens listed at page 59 of MAHADY there is not a single one described as multi-resistant. MRSA is not mentioned in this context, either. Accordingly, MAHADY neither teaches nor suggests that oil of coriander has an anti-microbial or inhibiting effect on these pathogens. This is why one of ordinary skill in the art does not gain the particular insight which s/he needs to supplement the knowledge that is missing from LILLEY, i.e., that the microbe-caused disease is linked to MRSA and multi-resistant pathogens.

It also must be taken into account here that LILLEY teaches the treatment of diseases selected from dental caries, gingivitis and/or periodontal disease by oral administration of compositions of, *inter alia*, oil of coriander in the oral cavity whereas MAHADY tries to answer the question whether medicinal plants are a potential alternative for conventional antibiotics in animal husbandry, i.e., has nothing at all to do with the treatment of dental caries, gingivitis and/or periodontal disease. The Examiner still has not explained why one of ordinary skill in the art would nevertheless consider the teachings of LILLEY and MAHADY in combination.

Applicants submit that for at least all of the foregoing reasons and the additional reasons set forth in the responses to the previous Office Actions, LILLEY in view of MAHADY fails to teach or suggest that oil of coriander is effective for treating diseases caused by *Staphylococcus aureus* and/or multi-resistant pathogens, even if one were to assume, *arguendo*, that one of ordinary skill in the art would be motivated to combine the teachings of LILLEY and MAHADY. In view thereof, withdrawal of the instant rejection under 35 U.S.C. § 103(a) over these documents is warranted.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, wherefore an early issuance of the Notices of Allowance and Allowability is respectfully solicited. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,
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July 21, 2011
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